BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT
ACTIVITIES DURING THE REGULATORY REVIEW PERIOD
FOR **GEODON CAPSULES (ZIPRASIDONE HYDROCHLORIDE MONOHYDRATE)**

(For explanation of abbreviations, see last page)

DATE	ACTIVITY	COMMENTS
4/2/90	Submission to FDA	IND for ZELDOX Oral (IND-34,629); IB (version 3/90); New Protocol (#128-001:001-501), New Investigator; Mfg. submission; Preclinical. Reports
4/9/90	Correspondence from FDA	Assigning IND 34-629
8/10/90	Submission to FDA	New Protocol (#002-501); New Investigator
9/21/90	Submission to FDA	(#001-501); Clinician CV (Gerber); Mfg. submission
11/1/90	Submission to FDA	New Protocol (#004-503), New Investigator; Mfg. submission.
11/7/90	Correspondence from FDA	Requests and suggestions with regard to Pharmacology & Mfg./Control
11/30/90	Submission to FDA	Protocol Amendment (#002);Mfg. submission.
1/11/91	Submission to FDA	Response to 11/7/90 Letter (Leber), 11/29 Telcon, 11/30 Fax (DeGeorge): re :Exclude WCBP until success with segment I/II studies; conduction parameters for preclinical. Studies; Preclinical. per Div. Request
3/18/91	Submission to FDA	New protocol (#005-501), New Investigator
4/2/91	Submission to FDA	CMC Response amendment re: 1/11/91 submission, 11/7/90 Letter
4/29/91	Submission to FDA	Annual Progress Report
5/21/91	Submission to FDA	Monthly Report (Prot.#101), Generic Label, Blister Pack 101:505; Synopses 128-002/004/005; Mfg. Submission; Preclinical. reports
6/28/91	Submission to FDA	New Protocol, New Investigator (#101-507; 101-508)
7/30/91	Submission to FDA	Investigator's Brochure (version 6/91)
8/7/91	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31):Protocol Amendment (#101) New Investigators (101-506/509/510); Mfg. submission.
9/19/91	Submission to FDA	New Protocol (#006-599); New Investigator; Mfg. submission.
11/4/91	Submission to FDA	Protocol Amendment (#101)
11/21/91	Submission to FDA	New Protocol (#008-511), New Investigator; Letter Of authorization (Wong) for 11C-Raclopride
1/21/92	Submission to FDA	New Protocol (#102-513), New Investigator; Clinician's CV (Ko)
3/3/92	Submission to FDA	Protocol amendment (#102); Mfg. submission
4/2/92	Submission to FDA	Monthly Report (21 CFR 312.30); New Investigator (#102-514); Protocol amendment (#101-510)
4/6/92	Submission to FDA	New Protocol (#007-515), New Investigator
5/8/92	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31); New Investigator (#102-512); Final report (#004); Mfg. submission.
5/20/92	Submission to FDA	New Protocol, New Investigator (#104-518); Generic Labels; Clinician's CV (Chandler)
6/22/92	Submission to FDA	Monthly Report (21 CFR 312.30) Corrected copy of Prot. #104; New Investigators (#104-517/520/528/529)
6/26/92	Submission to FDA	New Protocol (#009-532), New Investigator; Generic Labels
7/13/92	Submission to FDA	Annual Progress Report (2/92)
7/22/92	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators (#104-516/523); change in FDA 1572 Form
7/31/92	Submission to FDA	Protocol amendment (#104)
8/13/92	Submission to FDA	Monthly Report (21 CFR 312.30): New Investigators (#104-521/522/524/526/527/530/531)
8/17/92	Submission to FDA	New Protocol (#105-534), New Investigator
8/19/92	Submission to FDA	New Protocol (#011-599), New Investigator; Mfg. submission.
9/14/92	Submission to FDA	Monthly Report (21 CFR 312.30): Amended Protocol (#102); New Investigator

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		(#104-513); Protocol Amendment (#104-516)
9/17/92	Submission to FDA	Investigator's Brochure Addendum 1 (Version 9/92)
10/6/92	Submission to FDA	Range finding studies in rats & mice; dose rationale for carcinogenicity studies (data summaries): #92-720-15, 92-720-18, 92-720-16, 92-720-19; Proposed and standard protocol for the oncogenicity studies
10/9/92	Submission to FDA	Monthly Report (21 CFR 312.30): Amended Protocol (#009&105); New Investigators (#104-519/525)
11/13/92	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators (#104-535/536/537/538) Preclinical. Reports (91094/95, 92-720-11)
11/20/92	Submission to FDA	Protocol Amendment (#102)
11/25/92	Submission to FDA	New Protocol (#013), New Investigator (#013-501)
12/14/92	Submission to FDA	New Protocol (#010), New Investigator (#010-599); Preclinical. Reports
12/23/92	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigator(#102-533); Mfg. Submission.
1/18/93	Submission to FDA	New Protocol (#104E-523), New Investigator
1/22/93	Submission to FDA	New Protocol (#106), New Investigators (#106-539/541)
2/11/93	Submission to FDA	Monthly Report (21 CFR 312.30), Investigator Letter Re: PT death; Protocol Amendment (#105)
2/25/93	Submission to FDA	Protocol Amendment (#013); New Investigators (#106-540/546/550)
3/2/93	Submission to FDA	Protocol Amendment (#102)
3/24/93	Submission to FDA	Monthly Report (21 CFR 312.30): New Investigators (#106-542/548/552/553)
4/1/93	Submission to FDA	IND Safety Report; Adverse Event (#104), Example Letter to Investigators
4/20/93	Correspondence from FDA	RE: 4/8/93 Telecon (Hossain) re: Completed Studies: Biopharmaceutic Reviewer's Comments/Recommendations
4/29/93	Submission to FDA	Monthly Report (21 CFR 312.30): Protocol Amendment (#120), Generic Label; New Investigators, Revised 1572 Forms (#104E-526, 106-543/544/547/549/551; 104-519/522, 104E-523)
5/5/93	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators, changes in FDA 1572 Forms (104E-537, 106E-549; 101-506/510, 104-531)
6/22/93	Submission to FDA	Annual Progress Report
7/9/93	Submission to FDA	Response to 4/20/93 Letter Re: Protocols 006/011/013
7/9/93	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators, (#104E-513/516/529, 106-509/555/556, 106E-551/553); IB (version 6/93 Addendum 2); Letters re: Export Waiver (Nightingale & Limoli)
7/19/93	Submission to FDA	New Protocol (#015-557), Pharmacology/Toxicology Response
7/20/93	Submission to FDA	New Protocol, New Investigator (#016-560)
7/28/93	Correspondence from FDA	Re: Export Waiver: Authorization to ship drug to Japan)
8/11/93	Submission to FDA	New Protocol, New Investigator (#014-560), Mfg. submission
8/12/93	Submission to FDA	OCF Guidelines for inclusion of WCBP; New Protocol, New Investigator (#109-564) Protocol Amendments (#015/104/104E/106/106E), Mfg. Subm., Preclin. Rpts.
9/1/93	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Protocol, New Investigators, Protocol Amendment (#106E-542/552; 104-513/527/529/531/536)
9/7/93	Correspondence from FDA	Re: 8/93 Telcon & 7/20/93 Subm.:Comments re Prot. 016 and Inclusion of WCBP
10/1/93	Submission to FDA	Protocol Amendment (#015)
10/8/93	Submission to FDA	Investigator's Brochure (version 9/93) Addendum 3
10/26/93	Submission to FDA	Protocol Amendments (#106 & 106E)
10/29/93	Submission to FDA	Protocol Amendment (#016); Mfg. Subm.
11/09/93	Submission to FDA	New Protocols, New Investigators (#109E-572; 110-500/537)
11/18/93	Submission to FDA	Monthly Report (21 CFR 312.30) New Protocols, New Investigators, Changes to

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		FDA Form 1572, Amendments (#109-520/562/565/566/567/568/570/572, 110-540; 016-560 MOD)
11/30/93	Submission to FDA	New Protocols (#018/019/020) New Investigators (#018-5005, 019-501, 020-5003)
12/9/93	Submission to FDA	New Protocols (#021/022/023/024) New Investigators (#021/022/023-599, 024-502) Mfg. Submission.
1/12/94	Submission to FDA	Protocol Amendment (#110) Change to 1572
1/21/94	Submission to FDA	End of Phase II MTG Pkg.: Clin./Preclin. Summary; Core Study Rpts. For Protocols #101/104/106;
2/14/94	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators (#015-5002, 106E-555) New Protocols (#109E/520/564/566) Changes to 1572 (#104E-537MOD) Mfg. Submission., Preclinical. Reports
3/7/94	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators (#106E-509/556)
3/21/94	Submission to FDA	Annual Progress Report
4/1/94	Submission to FDA	New Investigator (#111-573)
4/11/94	Correspondence from FDA	Re: Inclusion of WCBP to Clinical Studies
4/18/94	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators, Changes to 1572 Forms (#109E-568; 010-599, 104-531, 106/106E-539 MODS), Mfg. Submission Prot.#111 Generic Label
5/2/94	Submission to FDA	Protocol Amendment (#106E) Change to 1572
5/20/94	Submission to FDA	Protocols #114 & 115 for Div. Rev.; End Phase II Mtg. Minutes New Protocol, New Investigator (#017-5005); Publications to support radiolabelled study
6/9/94	Submission to FDA	Investigators Brochure (version 6/94) New Protocol, New Investigator (#027-610)
6/17/94	Submission to FDA	Response to 4/11/94 Ltr. Re: Pharmacology/Clinical Development; Example ICF; Change to 1572 (#017 MOD)
6/28/94	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators (#106E-540/550, 111-574)
6/29/94	Correspondence from FDA	RE: 3/24/94 End of PHASE II Mtg.; Comments/Recommendations re Pharmacology/Toxicology
7/7/94	Correspondence from FDA	Fax: Comments re Multiple Comparison Procedure in Prots 128-114/115, 159-103
7/8/94	Submission to FDA	New Protocol, New Investigator (#108-580)
7/20/94	Submission to FDA	New Protocol, New Investigator (#025-501)
8/1/94	Submission to FDA	New Protocols, New Investigator (#114/115, 114-587)
8/19/94	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators (#108-534/536/ 541/567/574/575/578/579/581/582/585/587/589/597/598/605/606/609, 114-587) 11 Changes to 1572 Forms (MODS), Mfg. Subm., Preclin. Reports
8/26/94	Submission to FDA	New Protocol, New Investigator (#029-599)
8/31/94	Submission to FDA	New Protocol, New Investigator (#116-574)
9/20/94	Submission to FDA	Changes to 1572 (#108)
9/21/94	Submission to FDA	New Protocol, New Investigator (#026-608)
10/3/94	Submission to FDA	Response to 7/7/94 Request for an approach to control family-wise error rate
10/18/94	Submission to FDA	New Protocol, New Investigator (#117-669)
10/21/94	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators (#108, 114, 115), Mfg. Submission. (#108 and 115); Generic Labels
10/26/94	Submission to FDA	Changes to 1572 (#114)
11/4/94	Submission to FDA	Changes to 1572 (#115)
11/28/94	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators, New Protocol (116B) #026/108/114/115/116B/117) Changes to 1572 Forms (6)

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12/1/94	Submission to FDA	New Protocol, New Investigator (#028-693)
12/19/94	Submission to FDA	Investigator's Brochure (version 11/94)
12/22/94	Submission to FDA	Protocol Amendment (#108)
12/23/94	Submission to FDA	Safety Report: Pharm./Tox. Info re: 2 yr. chronic mice
1/11/95	Submission to FDA	New Protocol, New Investigator (#032-557)
1/12/95	Submission to FDA	Safety Report: Observation during evaluation of rabbit reproductive study III (Teratology)
1/16/95	Submission to FDA	Protocol XXX for Div. Rev.
1/25/95	Submission to FDA	Investigator's Brochure Addendum (version 1/95)
1/31/95	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators (#108/114/115/116B/117); Changes to 1572 Forms; Mfg. Submission.
2/6/95	Submission to FDA	Protocol Amendments (#115/116B)
2/14/95	Submission to FDA	New Protocol, New Investigators (#031-599); Protocol Amendment (#108)
2/17/95	Submission to FDA	Protocol Amendment (#117)
2/21/95	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators (#108/114/115/116B) Changes to FDA 1572 Form (#114-658); Protocol 108 Generic Lab
3/14/95	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators (#115/116B/117); Changes to 1572 Forms
4/10/95	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators (#114/115/116B/117); Changes to 1572 Forms
4/11/95	Submission to FDA	Safety Report; not considered "serious" AR (Polish PT w/grand mal seizure)
4/18/95	Submission to FDA	Protocol Amendment (#111)
4/20/95	Correspondence from FDA	Request for meeting to discuss protocol design issues
5/12/95	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators (#114/116B/117); Changes to 1572 Forms; Mfg. Submission.
5/16/95	Submission to FDA	Annual Progress Report (1/95); Preclinical. Submission.
5/17/95	Submission to FDA	New Protocol, New Investigator (#118-703)
5/30/95	Submission to FDA	New Protocol, New Investigator (#108E-534)
6/9/95	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31); New Investigators (#115/116B/117) Changes to 1572 Forms (#026, 114); Mfg. Subm., Preclin. Submission.
6/16/95	Submission to FDA	Request for a meeting
6/23/95	Submission to FDA	Investigator's Brochure Addendum 2 (version 6/95)
6/29/95	Submission to FDA	Proposal for Brief; Summary Type Study Rpts. (Draft Study 014); Desk Copy Hardeman
7/27/95	Correspondence from FDA	Request to have detailed written response to 7/7/94 letter
8/1/95	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators (#108/108E/114/115/116B/117/118) Changes to 1572 Forms; Preclin. Subm.
8/11/95	Submission to FDA	Response to Div. Comments of 7/17/95; Draft Protocol Amendment for #114 for Review
8/25/95	Submission to FDA	New Protocol, New Investigator (#030-700)
9/5/95	Submission to FDA	New Protocol, New Investigator (#035-599)
9/19/95	Submission to FDA	New Protocol, New Investigator (3036-5005); Amended Protocol (#116B)
9/29/95	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators (#108/108E/114/115/116B/117/118); Changes to 1572 Forms; Mfg. Subm.; Preclin. Drug Metabolism Reports
10/20/95	Submission to FDA	New Protocol, New Investigator (#034-501); Protocol Amendment (#117)
10/26/95	Submission to FDA	Mfg. Submission
10/30/95	Submission to FDA	New IND for Intramuscular Formulation
11/3/95	Submission to FDA	Investigator's Brochure (version 10/95)

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11/30/95	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31); New Investigators (#108/115/116B/117/118); Changes to 1572 Forms; Mfg. Submission.
1/12/96	Submission to FDA	Investigator's Brochure Addendum (version 12/95)
1/16/96	Submission to FDA	New Protocol (#122)
1/24/96	Submission to FDA	Monthly Report (21 CFR 312.30); New Investigators (#030/108E/115/116B/118) Protocol Amendments (#026/108/114/115/116B/117)
2/1/96	Submission to FDA	Preclinical Submission
2/5/96	Submission to FDA	Request for copies of 1/16/96 Submission to both INDs (2 desk copies)
2/16/96	Submission to FDA	Mfg. Submission
3/5/96	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31); New Investigators (#108/108E/115) Protocol Amendments (#008/106/108/108E/114/115/116B/117); Preclin. Subm.
3/15/96	Submission to FDA	Response.: Sample Subgroup (Age, Gender, Race) Tabulations & Analyses for Review & Comment (2 desk copies)
3/20/96	Submission to FDA	New Protocols, New Investigators (#040-599/043-599)
4/2/96	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Investigators (#108/115/116B) Protocol Amendments (#108/108E/114/115/116B/117); Quintiles, CRO for 108 & 108E Studies; 4 Preclinical. Reports
4/8/96	Submission to FDA	Pre-NDA Meeting Pkg; (2 desk copies)
4/19/96	Submission to FDA	Protocol Amendment (#040)
4/24/96	Submission to FDA	Protocol Amendment (#122)
5/1/96	Submission to FDA	New Protocol, New Investigator (#041-748)
5/6/96	Submission to FDA	Monthly Report (21 CFR 312.30) New Investigators (#108E/115/116B/122); Changes to 1572 Forms; Generic Label for #122
5/9/96	Facsimile from FDA	Guidelines/Templates of desired data displays for the NDA
5/10/96	Submission to FDA	Tumor Data from Rat & Mouse in electronic form; (desk copy/diskettes)
5/23/96	Submission to FDA	New Protocol, New Investigator (#039-746)
5/31/96	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31); New Investigators (#116B/122); Protocol Amendments (#106E/108/108E/114/115/116B/117/118); Mfg. Subm.
5/31/96	Submission to FDA	Annual Progress Report (2/96)
6/6/96	Submission to FDA	Pre-NDA Meeting Minutes (4/25/96); Request for Laughren's Templates of Safety Tables & for Division's Meeting Minutes (desk copy)
6/12/96	Fax from FDA	Laughren's Safety Table Templates
6/25/96	Submission to FDA	Request for Review and Comment re: Proposed Data Display (Patient Flowsheet); desk copy
6/25/96	Submission to FDA	Monthly Report (21 CFR 312.30); New Investigators (#108/116B); Changes to 1572 Forms
6/27/96	Submission to FDA	New Protocol, New Investigator (#044-744); Mfg. Submission.
7/2/96	Submission to FDA	Submission of Preferred (ZELDOX) & Alternate (GEODON) Tradename to CDER Labeling & Nomenclature Committee; (desk copy)
7/8/96	Facsimile from FDA	Comments re Proposed Data Display (Patient Flowsheet sent on 6/25/96); Need all collected lab data included in these displays.
7/10/96	Correspondence from FDA	Copy of meeting minutes from 5/20/96 meeting
7/19/96	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31) New Protocol (#047), New Investigators (#047/108E), Amendments (#108/114/115/116B/117); Preclin. report
7/26/96	Submission to FDA	Protocol Amendment (#108E)
8/06/96	Submission to FDA	Request for Waiver of Submission of Hardcopy CRF & Tabulation for the NDA; desk copy
8/13/96	Submission to FDA	Response: Additional copies of Pre-NDA Mtg. Pkg. (filed 4/8/96) to Dr. Bajewa

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8/13/96	Submission to FDA	Safety Report: Death of a Pt. in a non-IND Study; Preliminary review of the incidence of cardiovascular & unexplained deaths
8/16/96	Submission to FDA	Monthly Report (21 CFR 312.30) New Protocol (#045), New Investigators (#045/108/108E), Amendments (#026/039/108/115/116B/117)
8/21/96	Correspondence from FDA	Request to submit case reports for 13 deaths reported in the Annual Report
8/29/96	Submission to FDA	Protocol Amendment (#115)
9/3/96	Submission to FDA	New Protocol (#121)
9/4/96	Submission to FDA	New Protocols (#048, 049), New Investigators (#048/049)
9/4/96	Facsimile from FDA	Labeling and Nomenclature committee approval of the proposed trade names ZELDOX and GEODON
9/18/96	Submission to FDA	Response: Additional information re 13 subject deaths summarized in AR (5/31/96); desk copy
9/30/96	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31); Investigator's Brochure (version 9/96) New Investigators (#026/030/116B) Amendments (#026/108E/115/116B/117); Metabolism Report
10/23/96	Submission to FDA	re Subm. 8/13/96; Mortality rate to be provided at the time of NDA submission
10/30/96	Submission to FDA	Pre-NDA Mtg. Pkg. - CMC; Mtg. set for 11/25/96 to seek Division input on proposed strategies to address CMC issues
10/31/96	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31); New Investigator (#116B); Amendments (#108/108E/115/116B/117/122); Preclin. & Mfg. Reports
11/04/96	Submission to FDA	Protocol Amendment (#045); Mfg. Report
11/12/96	Submission to FDA	New Protocol, New Investigator (#042-749)
11/15/96	Correspondence from FDA	Draft guidance document to be used for the clinical safety review of NDA submissions; (Reviewer Guidance for conducting a Clinical Safety Review of a new product application and preparing a report on the review
11/18/96	Submission to FDA	Response: Sample efficacy and safety datasets on diskette with hardcopy of SAS contents procedure & variable names; (desk copy)
12/5/96	Submission to FDA	Monthly Report (21 CFR 312.30 and 312.31); New Investigator (#108E); Amendments (#106/106E/108E/116B/117); Preclin. Report
12/10/96	Submission to FDA	Adverse Event: Congenital abnormality in a neonate whose mother was exposed to a single dose
1/14/97	Submission to FDA	Minutes of CMC Pre-NDA Mtg. (11/25/96) & Teleconference (12/5/96); 2 desk copies
1/16/97	Submission to FDA	Confirm NDA number: NDA-20-825
1/30/97	Submission to FDA	Monthly Report (21 CFR 312.30); Amendments (#048/108/108E/115/116B/117)
2/05/97	Submission to FDA	Response: Proposal for NDA ECG Data Presentation; (desk copy)
2/10/97	Submission to FDA	New Protocols (#125 IM & 127E IM);
2/12/97	Submission to FDA	New Protocol, New Investigator (#050-748); Mfg. Report
2/13/97	Submission to FDA	New Protocol, New Investigator (#126-669)
3/03/97	Submission to FDA	Mfg. Report
3/7/97	Facsimile from FDA	Memo regarding review of sample QT Table proposed for NDA Submission and request for comment
3/17/97	Submission to FDA	Initial NDA-ZELDOX to FDA (Letter dated 3/18/97)
4/11/97	Submission to FDA	Response to Query 1: ECG Data for review (desk copy & diskette)
5/2/97	Submission to FDA	Data re: Impurity profile & specifications relating to commercial drug product; data re: Hydrochloride Salt of CP-78459
5/12/97	Correspondence from FDA	Request to reanalyze the efficacy data for 128-114 omitting data from Borison & Diamond; re-evaluate their safety data & determine if it is consistent with safety data

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		from other investigators
5/28/97	Submission to FDA	ECG Tracings (desk copy) re: 4/11/97 submission
6/02/98	Submission to FDA	Annual Progress Report (5/97)
6/6/98	Submission to FDA	Response: Efficacy and Safety Tables rerun without Borison/Diamond data; (desk copy)
6/18/97	Submission to FDA	Response to Query 6: List of investigators from well-controlled studies (include. number of subjects) and corresponding protocols (101/106/114/115/303)
7/18/97	Submission to FDA	Reanalysis of additional efficacy tables (#128-114) excluding Borison Data
7/23/97	Submission to FDA	Additional information re:trial sites and investigators for studies 114/115/303
7/28/97	Submission to FDA	QC Sampling plan for Zeldox Capsules
8/22/97	Submission to FDA	List of Pfizer Zeldox Team Members who may be contacted directly by FDA re: NDA reviewer questions
8/25/97	Correspondence from FDA	Request to update SAS software before expiration on 9/15/97
8/25/97	Correspondence from FDA	Request for desk copies of Ziprasidone NDA submissions of 4/11 and 5/28/97
8/29/97	Submission to FDA	Safety Update
9/4/97	Facsimile from FDA	Request for Electronic files of the computer programs used in longitudinal analyses of treatment effects for primary efficacy variables if data and/or format different from CANDA Submission.; Submit SAS Log and output of analyses results
9/9/97	Facsimile from FDA	Request for clarification of discrepancies in the number of subject deaths reported in NDA vs. 4mo. Safety Update; example format for a table for the SE studies; request to resubmit Table H.2.1. to describe entire database including all studies in safety update
9/11/97	Submission to FDA	Response re 9/4/97: Electronic files of computer programs used to conduct longitudinal analyses of clinical trials; SAS Log & SAS Output of these analyses
10/3/97	Correspondence from FDA	Need to determine the extent to which Ziprasidone prolongs the QT interval; ECG data in NDA show that Ziprasidone is associated with dose dependent increase in the QTC; request to conduct in vitro studies.
10/7/97	Submission to FDA	Preclinical Report #97-720-39
10/10/97	Submission to FDA	Response to Young request (9/5/97): Additional information for #303-180
10/14/97	Submission to FDA	Study Report #302
10/16/97	Submission to FDA	Safety Report: Adverse Event in Study ZIP-JP-95-601 57-2; ICF Addendum
10/17/97	Submission to FDA	Response (Div. Ltr. 10/3/97): Additional information re ECG Data and QTC intervals.
10/23/97	Submission to FDA	Response: Pre-Approval Inspection Comments; corrected pages to Initial NDA Section 3 (Pg 450-455, exclusive of 452).
10/24/97	Submission to FDA	Comprehensive Table delineating the clinical trials included in NDA & 4-Month Safety Update; Update of NDA Table H.2.1.
10/24/97	Submission to FDA	ECG Data from Study #303
10/31/97	Submission to FDA	Response: to Pre-Approval inspection comments; several items related to the manufacturing procedure & test procedure validation data for the drug product will need to be corrected or clarified
11/7/97	Submission to FDA	Response: re telcon Al-Habet 10/24&28/987; re Studies #026 & 027
11/13/97	Submission to FDA	Response: Dr. Morgenroth's report re Ziprasidone's effect on the ECG
11/18/97	Submission to FDA	Response: Additional information pertaining to the assessment of lab data in the NDA; use of "TIER 1" "TIER 2" criteria; procedure for normalization of all lab values & Pfizer standard reference ranges used;
12/16/97	Submission to FDA	re telcons 12/12 & 12/15/97:Intent to submit reports for Studies # 044/122/050
12/17/97	Submission to FDA	Confirming that the worst post-baseline lab value was used in the assessment of clinically significant abnormalities

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12/19/97	Submission to FDA	Response to Freed Request: Additional information and clarification pertaining to reproductive toxicology studies and data on room temperature stability, concentration & homogeneity of the ziprasidone suspensions used in these studies.
12/19/97	Submission to FDA	Additional information re subjects who became pregnant while on study drug
1/23/98	Submission to FDA	Pediatric drug interaction amendment: Study Rpts #044/122/050; draft package insert
1/26/98	Submission to FDA	Draft Briefing Package on ECG Findings
1/30/98	Submission to FDA	Response (Al-Habet 1/7/98): Individual dissolution data points for the respective capsule lots referenced in the NDA
1/30/98	Facsimile from FDA	Transmittal of consultation memos from HFD-110 on QT and QTC Interval Data
1/30/98	Submission to FDA	Preclinical replacement pages: #92-720-20/92-720-20C & 94-720-30
1/30/98	Submission to FDA	Study Reports #301 & 045
2/2/98	Facsimile from FDA	Forwarding slides and classification scheme for sudden deaths
2/9/98	Submission to FDA	Response: Clarification on procedures related to the capture and reporting of clinical trial data
2/11/98	Submission to FDA	Response (Al-Habet 2/11/98): Information regarding timing of ECGs relative to time of dosing in PH I/ III studies
2/13/98	Submission to FDA	Prolactin data for Ziprasidone and comparative agents from PH II/III Clinical Trial Database
2/13/98	Submission to FDA	Response (re 1/29/98 Mtg): ECG & Mortality data; results from related in vitro experiments
2/18/98	Submission to FDA	Updated patient narratives
2/18/98	Submission to FDA	re Young's 12/97 inspection of Poland site: additional information after site inspection
2/27/98	Submission to FDA	Response (Al-Habet/Bajewa 1/27 & 2/3/98): Data pertaining to drug product lot numbering and dissolution testing
3/20/98	Submission to FDA	Pre-Meeting Briefing Package
3/26/98	Submission to FDA	Response: Exposure data from trials conducted in Japan
3/26/98	Submission to FDA	Zeldox (Ziprasidone) capsules updated patent and exclusivity information
4/9/98	Submission to FDA	Response (Glass 4/3/98): Information regarding the inclusion of adverse events in the Zeldox Capsules NDA irrespective of the investigator's judgment of causality
4/24/98	Submission to FDA	Division request for electronic version
4/28/98	Submission to FDA	Safety Letter
5/1/98	Submission to FDA	Updated container and carton packaging
5/15/98	Submission to FDA	Protocol R-0585; Protocol 108E, 116B, 129 MODS, Protocol R-0547, R-0548, R-0553, R-0554, R-0555, R-0570, MODS, CMC;
5/15/98	Submission to FDA	Response: Resubmission of IND Safety Report
5/20/98	Submission to FDA	Response: Preclinical Data Relative to ECG Effects
5/27/98	Submission to FDA (IND)	Monthly Rpt.: New Investigator, Prot. R-0554; 108-692;116B-513 MOD
5/28/98	Submission to FDA (IND	Safety Report: Follow-up Info regarding ECG readings – Japanese subject (Safety ref: #9805913)
6/12/98	Submission to FDA (IND)	New Investigators for Prot R-0548/R-0585; 97-R-0230 MOD
6/17/98	Correspondence from FDA	Fax: Zeldox Action Letter (Non-Approvable Letter)
6/19/98	Submission to FDA	Request for meeting; notification of plans to amend application
6/22/98	Submission to FDA (IND)	Monthly Rpt: Prot. R-0553, 97-R-0090 MOD; Prot. R-0554; 97-R-0272 MOD; 108-686; 108e-720 MOD
6/26/98	Submission to FDA (IND)	Prot. R-0553/R-0554/R-0555 MODs
7/13/98	Submission to FDA (IND)	New Investigators for Prot. R-0548, 0570, 0585
8/3/98	Submission to FDA	Final Safety Update
8/7/98	Submission to FDA (IND)	Prot. 055-802; Mfg.

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8/17/98	Submission to FDA	Final Safety Update & Electronic Version
8//17/98	Submission to FDA	Response: Pre-Meeting Briefing Package
8/19/98	Submission to FDA (IND)	New Investigators for Prot. R-0548, R-0570, R-0585
8/28/98	Correspondence from FDA	Fax: Meeting minutes from 8/21/98 and information request for individual line listings for fetuses for the teratology studies in rat and rabbit for CP-217,861-02
9/2/98	Submission to FDA (IND)	Monthly Rpt.: 116B-606, 042-749 Mod. to 1572: 97-R-0263, 97-R-0225, 97-R-0228, 97-R-0229, 97-R-0246, 97-R-0302
9/23/98	Submission to FDA	Response: Draft Protocol 128-054; Minutes of 8/21/98 meeting regarding the design of an additional study
10/2/98	Submission to FDA (IND)	Monthly Rpt.: 108E Modifications; Prot. 116B Mod.; 116B-529/551/587/701 Mod.; 117-706 Mod.
10/23/98	Submission to FDA	Prot. 054; Mfg. Comparator Agents; Mfg. Placebo Cover Letter Only
10/27/98	Submission to FDA (IND)	Monthly Rpt.: New Investigators for Prot. R-0548, R-0570, 0585; R-0553/97-R-0090/0091/0096/0264Mod; R-0554/97-R-0273/0278/0281 Mod; R-0555/97-R-0293/0298/0301 Mod; 108/108E-567 Mod
11/11/98	Submission to FDA (IND)	Monthly Rpt. 054-794, 116B-592, New Investigators for Prot. R-0548, R-0570, R-0585
12/3/98	Submission to FDA (IND)	New Investigators for Prot. R-0548; R-0570; R-0585
12/16/98	Submission to FDA (IND)	Monthly Rpt. New Investigators for 054-782; New Investigators for R-0548; R-0570, R-0585
1/6/99	Submission to FDA (IND)	New Investigators for Prot. R-0548, R-0570, R-0585
1/21/99	Submission to FDA (IND)	New Prot. 056-5001
1/27/99	Submission to FDA (IND)	Mfg.
1/29/99	Submission to FDA (IND)	New Investigators for Prot. R-0548, R-0570, R-0585
2/5/99	Submission to FDA	Monthly: 054-602; Mfg.
2/5/99	Submission to FDA	Final Report 117
2/8/99	Submission to FDA (IND)	Monthly Rpt.: New Investigators for Prot. R-0548/R-0570/R-0585
2/19/99	Submission to FDA (IND)	Monthly Rpt.: Prot. R-0548 Mod; Prot. R-0570 Mod; Prot. R-0585 Mod; Prot. R-0553 Mods; Prot. R-0554 Mods; Prot. R-0555 Mods
3/1/99	Submission to FDA	Proposal for final Safety Update #2
3/2/99	Submission to FDA	Safety Report: 50 yr. old Australian Male; intentional overdose; Ref.#9907409
3/8/99	Submission to FDA (IND)	Monthly Rpt.: 054-529/5006; 116B-603
3/16/99	Submission to FDA	Follow-up Safety Report
3/18/99	Submission to FDA	Monthly Rpt.: 116B-594; New Investigators for Prot. R-0548, R-0570, R-0585
3/30/99	Submission to FDA (IND)	Monthly Rpt.: 054-782/794/5006 Mod; 108E-686 Mod; 116B-637 Mod
3/30/00	Submission to FDA (IND)	Monthly Rpt.: R-0548-97-R-3544, R-0570-98R-4044, R-0585-98-R-3044 New Investigators; Clinician CV (O'Sullivan)
4/5/99	Submission to FDA (IND)	Monthly Rpt.: 24 Mods for Prot. R-0548, 23 Mods for Prot. R-0570; 23 Mods for R-0570, 23 Mods for R-0585; 5 Mods for 0553; 4 Mods for R-0554, 4 Mods for R-0555
4/7/99	Submission to FDA (IND)	New Investigators for R-0548, R-0570, R-0585, 97-R-3538/98-R-4038/98-R-3038/97-R-3502/98-R-4002/98/R-3002 Mod
4/14/99	Submission to FDA	Prot. 054 Modifications
4/22/99	Submission to FDA (IND)	R-0554 Prot. Mod.; New Investigators for Prot. R-0570, R-0585; 97-R-3511/97-R-0230/97-R-3544/98-R-4044/98-R-3044/97-R-3531/98-R-4031/98-R-3031/97-R-0280 Mod
5/5/99	Submission to FDA (IND)	Monthly Rpt.: 054-782/602/735, 116B-735/663/682/579/577/633 Mod
5/19/99	Submission to FDA (IND)	Monthly Rpt.: 116B-522/716/5011; New Investigators for Prot. R-0548; R-0570; R-0585

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5/20/99	Submission to FDA (IND)	Monthly Rpt: New Investigator for Prot. R-0548; R-0570; R-0585
5/24/99	Correspondence from FDA	Request for complete description of patient overdose incident incl. ECG, QT measurements, vitals and treatment
5/26/99	Correspondence from FDA	Request for a report to IND 34,629 cross-referencing 49,045 and 54,297; summarizing pertinent safety data
6/1/99	Submission to FDA	Response: Proposed pediatric study request
6/8/99	Submission to FDA	APR (May 99)
6/8/99	Submission to FDA (IND)	Monthly Rpt.: New Investigators for R-0548; R-0570; R-0585; 116-692; 97-R-3563/98-R-4063/98-R-3063 Mod; Mfg.
6/9/99	Submission to FDA	Preclinical
6/9/00	Submission to FDA (IND)	Monthly Rpt.: 97-R-0093 Mods
6/23/99	Submission to FDA (IND)	Prot. 116B Mod
6/24/99	Submission to FDA	Response: Request for meeting regarding QTc data and NDA resubmission
6/28/99	Correspondence from FDA	Letter: Responding to our 6/1/99 Pediatric Study Request
6/30/99	Submission to FDA (IND)	Monthly Rpt.: 116B-719; New Investigators for R-0585; 98-R-3055/97-R-3510/98-R-4010/98-R-3010/98-R-3511/98-R-3011/97-R-0090/97-R-0272/97-R-0292/97-R-3544/98-R-4044/98-R-3044 Mods
7/1/99	Submission to FDA	General Correspondence: Dr. Nakra's site
7/26/99	Submission to FDA (IND)	116B-578, 97-R-3503, 98-R-3003/4003, 97-R-0230/3510/3521, 98-R-3021/4021, 97-R-0266, 97-R-3525, 97-R-0095/0277/0297, 97-R-3538, 98-R-4038/3038, 97-R-3530, 98-R-4030/3030, 97-R-3550, 98-R-4050/3050 Mods
7/30/99	Submission to FDA (IND)	Monthly Rpt.: 108-595 Mods, 108-576 Mod
8/25/99	Submission to FDA	Final Safety Update #2
9/2/99	Submission to FDA (IND)	Monthly Rpt.: 108E-719/720 Mods, 116B-556 Mod, 97-R-3505, 98-R-4005/3005, 97-R-3508, 98-R-3008, 97-R-3517, 98-R-4017, 98-R-4025, 98-R-3025, 97-R-3502, 98-R-4002/3002, 97-R-0268/0281/0301, 97-R-3551 Mods
9/10/99	Submission to FDA (IND)	Monthly Rpt.: New Investigators for Prot. R-0548/R-0570/R-0585/R-0555; 97-R-0230,97-R-3547,98-R-3043,97-R-3516,98-R-4016/3016,98-R-4024/3024, 97-R-3534,98-R-4034/3034
9/13/99	Correspondence from FDA	Letter: Response to Dr. Harrigan's 8/24/99 letter to Dr. Laughren regarding plans for additional analyses to correct the QT data obtained in Study 054
9/13/99	Submission to FDA (IND)	Prot. A1281018;Clinician CV-Harty
9/15/99	Submission to FDA	Response: Proposal for routine monthly safety reporting
9/20/99	Submission to FDA	Additional information regarding IND Safety Report 3/2/99 and 3/16/99
9/23/99	Submission to FDA (IND)	Monthly Rpt.: A1281018-602/782/794;97-R-0273/97-R-0091/97-R-0293/ 97-R-3549/98-R-4049/3049/97-R-3524 Mods
10/11/99	Submission to FDA (IND)	Monthly Rpt.: A1281018-5006;97-R-3509/98-R-3009/97-R-0091 Mods
10/20/99	Submission to FDA (IND)	Monthly Rpt.:108E-557/574/588/716 Mods;116B-529/604 Mods
10/22/99	Submission to FDA (IND)	IB (October 1999)
10/27/99	Submission to FDA (IND)	Monthly Rpt.: New Investigators for R-0555;97-R-3531/97-R-3524/97-R-3537/ 97-R-3538/97-R-3501/98-R-4012 Mods
11/5/99	Submission to FDA	Response: Monthly Safety Report
11/29/99	Submission to FDA	Response: Monthly Safety Report
11/30/99	Submission to FDA (IND)	Monthly Rpt.:A1281018-0529;New Investigator for R-0585;97-R-0425 Mod; 98-R-3042 Mod
12/6/99	Submission to FDA	Request for meeting on QTc data and NDA resubmission
12/23/99	Submission to FDA	Response: Jan. Monthly Safety Report
12/23/99	Submission to FDA (IND)	Mfg.
12/24/99	Submission to FDA	Response: Proposal for IB and ICF revisions and collection of additional ECG data

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12/24/99	Submission to FDA (IND)	Study Rpt 128-054 (V:02-Dec-99)
1/11/00	Submission to FDA (IND)	New Investigators for R-0548;128-116B-681
1/13/00	Correspondence from FDA	Fax: Changes to the wording of 12/6/99 Fax
1/13/00	Submission to FDA (IND)	Prot .R-0548 Mods
1/21/00	Submission to FDA	Response: Monthly Safety Report
1/21/00	Submission to FDA	General Correspondence: Proposed Investigator Letter
1/28/00	Submission to FDA	General Correspondence: Proposed Investigator Letter
2/8/00	Submission to FDA	General Correspondence: Dr. Michorzewski Site 0269
2/22/00	Submission to FDA (IND)	Monthly Rpt.:New Investigators for R-0548;97-R-3566/97-R-3521/97-R-3547/ 98-R-4047/98-R-3047/97-R-3530/98-R-4030/98-R-3030 Mods
3/6/00	Submission to FDA	Response: Monthly Safety Report
3/10/00	Submission to FDA	NDA Resubmission
3/15/00	Submission to FDA	IB (March 00)
3/23/00	Submission to FDA (IND)	Monthly Rpt.:New Investigators for R-0585;97-R-3505/3545/3563/98-R3045/ 4045/ 97-R-3508/3535/98-R-3043/97-R-3511/98-R-4011/97-R3512/3514/3516/3544/3520/ 0425/0094/0296/3525/98-R-4025/3025/3058/4048/3048/97R3548/ 3549/ 0089/ 0275/3529/3540/98-R-4040/3040
3/28/00	Correspondence from FDA	Fax: Letter regarding questions on submission date of Safety Update 1 and requesting amendment submission on various items in March 10 submission
3/29/00	Submission to FDA	Response: Monthly Safety Report
4/4/00	Submission to FDA (IND)	Monthly Rpt.:New Investigators for R-0570;98-R-4021/98-R-4027 Mods
4/6/00	Submission to FDA	Response: NDA Amendment for Dr. Glass
4/17/00	Submission to FDA	Response: Additional information for Dr. Glass; mortality table, draft line listings
4/18/00	Submission to FDA (IND)	Prot .108E Mod
4/19/00	Correspondence from FDA	Fax: Memo requesting patient demographics (age/gender), drug concentrations and QT measurements for ziprasidone, thioridazine, quetiapine, risperidone, and metabolite, haloperidol and olanzapine
4/19/00	Submission to FDA (IND)	Prot 116B Mod; Prot. R-0555 Mod
4/20/00	Submission to FDA	General correspondence: request for teleconference – AC planning
4/20/00	Submission to FDA (IND)	Monthly Rpt.: New Investigators for R-0548/R-0570/R-0585;98-R-4001/ 97-R-3501/98-R-3021/98-R-3027/97-R-3521/97-R-3527/97-R-3571 Mods
4/26/00	Correspondence from FDA	Fax: Reminder that the due date for background material for the July PDAC meeting is coming up
4/27/00	Correspondence from FDA	Letter: announcing a forthcoming mtg. of a Public Advisory Committee of the FDA
5/1/00	Correspondence from FDA	Letter: Requesting more extensive safety information for evaluating all atypical antipsychotics
5/2/00	Correspondence from FDA	Letter: regarding May 10 due date for background material exempt from public disclosure; contact Exec. Secy. Karen Somers in Sandy Titus' absence.
5/4/00	Submission to FDA	Monthly Safety Report (May 2000)
5/5/00	Correspondence from FDA	Letter: Requesting further information for Dr. Glass; narratives, case report forms, or patient summaries for various discontinuations derived from the sponsor's lists
5/8/00	Submission to FDA	Response: ECG data from Study 128-054 for Dr. Gabriel Robbie
5/16/00	Submission to FDA (IND)	Monthly Rpt.:New Investigator for R-0548, R-0570,R-0585
5/19/00	Submission to FDA	Response: Narratives, subject summary profiles, data tables
5/22/00	Submission to FDA	Response: to Dr. Glass' 3/28/00 request; syncopal event narratives
5/24/00	Submission to FDA (IND)	Monthly Rpt.:New Investigators for R-0548/R-0570;97-R-0268/0281/ 0301/ 3523/ Mods; 98-R-4023/3023;97-R-3562 Mods; 98-R-4062/3062 Mods; 97-R-0265/0089 Mods; 108e-523/576/579/592/594/620/681 Mods
5/31/00	Submission to FDA (IND)	Prot. A1281043

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6/1/00	Submission to FDA	Zeldox Advisory Committee Draft Briefing Document
6/2/00	Submission to FDA	Response: Monthly Safety Report
6/2/00	Submission to FDA	Final Safety Update 3
6/7/00	Submission to FDA	Final Reports: 108, 301E, 302E, 304, 304E
6/15/00	Submission to FDA	Zeldox Advisory Committee Briefing Document
6/15/00	Submission to FDA (IND)	Monthly Rpt.:Prot R-0548/R-0570/R-0585 Mods; New Investigators for R-0548/R-0570
6/19/00	Submission to FDA	Response: Synopses of final study reports 108/117/301/301E/302/302E/304/304E
6/19/00	Submission to FDA	Response: Monthly Safety Report through 6/5/00
6/22/00	Submission to FDA	APR (2/5/00)
6/23/00	Submission to FDA	Zeldox Advisory Committee Briefing Document Cover Page Replacement
6/28/00	Correspondence from FDA	Letter: with materials that CDER provided to members of the PDAC in preparation for a July 19 meeting
6/29/00	Submission to FDA (IND)	Monthly Rpt.: A1281043-5029 New Investigators for 116B-5011/577/579/ 581/587/ 592/604/634/664 Mods
6/29/00	Submission to FDA (IND)	Prot. A1281037
7/12/00	Submission to FDA	Response: Hyperglycemia
7/13/00	Submission to FDA	Response: Monthly Safety Report
7/13/00	Submission to FDA	Zeldox AC Draft Sponsor Presentation Slides
7/14/00	Submission to FDA	Response: Mr. Hardeman's July 12 request for CRF 302-0057-0456
7/14/00	Submission to FDA (IND)	A1281037-5030; Mfg.
7/14/00	Submission to FDA (IND)	New Investigators for R-0548 and R-0570; 97-R-3505/98-R-4005/98-R-3005/ 97-R-3545/98-R-4045/97-R-3514/98-R-4014/97-R-3547/98-R-4047/98-R-3047/ 97-R-3569/98-R-4069/97-R-3501/98-R-4001/97-R-3538/98-R-4038/98-R-3038
7/18/00	Submission to FDA (IND)	Prot. A1281042; Clinician CV-Hsu
7/18/00	Correspondence from FDA	Draft Agenda for 7/19/00 PDAC
7/18/00	Correspondence from FDA	Final Agenda for Advisory Committee Meeting
8/9/00	Submission to FDA (IND)	Monthly Rpt.:128-116B-509; New Investigator for R-0570 and R-0585
8/16/00	Submission to FDA	Advisory Committee Slide Presentation
9/1/00	Submission to FDA	Response: to Dr. Freed query regarding M9 metabolite
9/1/00	Submission to FDA	Response: Monthly Safety Report
9/8/00	Correspondence from FDA	Ziprasidone Action Letter/Labeling (Approvable)
9/11/00	Submission to FDA (IND)	Monthly Rpt.: 128-116B-715;128-108eE516/578/594/603/692/719 Mods 128-116B-556/590/664Mods; 97-R-0297/3508/3509/3512/3530/3531/3543/ 3572 Mods; 98-R-3009/3030 Mods
10/2/00	Submission to FDA (IND)	Monthly Rpt.:97-R-3537/3539 Mod; 98-R-4009/4030/4031/4037/4043/4072 Mod
10/3/00	Submission to FDA	Response: Monthly Safety Report
10/20/00	Submission to FDA	Response: to Approvable Letter
10/20/00	Submission to FDA	Response: regarding Tradename
10/24/00	Submission to FDA	Response to FDA request for information regarding corrections to NDA Stability Data Tables
10/31/00	Submission to FDA	Response: Monthly Safety Report
11/21/00	Submission to FDA	Response: Monthly Safety Report
11/22/00	Submission to FDA (IND)	Monthly Rpt.:128-108E-509/584/601 Mods; 116B-5011/522/523/551/ 578/581/592/ 598/606/638/647/665/668/701/719/731/735 Mods
11/28/00	Submission to FDA	Updated Patent and Exclusivity Information
12/1/00	Submission to FDA	Response to request for Clarification of 10/20/00 submission
12/04/00	Correspondence from FDA	Fax:Draft Labeling Proposal
12/12/00	Submission to FDA	Nda Amendment - Proposed Product Labeling

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12/22/00	Submission to FDA	Information Amendment: Safety related AEM#A03034
01/02/01	Submission to FDA	Resp.: Monthly Safety Report
01/11/01	Submission to FDA	Response: To PPDRA's rebuttal of 11-24-00 Re: Acceptability of Zeldox Tradename
01/22/01	Submission to FDA	Monthly : Prot. A1281026
01/22/01	Submission to FDA	Monthly Rpt: Prot. R-0570 MOD;97-R-3566/98-R-4066/3066/97-R-3510/98-R-4010/3010/98-R-3056/3043/97-R-3511/98-R-4011/ 3011/98-R-3024/97-R-3570/98-R-4070/97-R-3516/98-R-4016/ 3016/97-R-3544/98-R-4044/97-R-3521/98-R-4021/302; 1 additional mod.; see submission
01/25/01	Submission to FDA	Response: Labeling statement concerning the dose response relationship of adverse events
01/26/01	Submission to FDA	Response: Dr. Laughren's request for inclusion of placebo in the statistical model
02/01/01	Submission to FDA	Response: Monthly Safety Update
02/05/01	Correspondence from FDA	Acknowledgment of FDA submissions – Approval letter and Labeling

ABBREVIATIONS

PT	Patient
WCBP	Women of child bearing potential
ICF	Informed consent form
AR	Annual report
CRO	Clinical Research Organization
CDER	Center for Drugs Evaluation and Research
ECG	Electrocardiogram
SAS	Statistical analysis software
MOD	Modification to Protocol
CMC	Chemistry, Manufacturing & Control
IB	Investigational brochure
APR	Annual Progress Report
PDAC	Psychopharmacologic Drug Advisory Committee
OPDRA	Office of Post-marketing Drug Risk Assessment